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SUBJECT: NANOTECHNOLOGY: EUROPEAN UNION VIEWPOINTS AND U.S.
OPPORTUNITIES FOR COLLABORATION

¶1. (SBU) Summary: The European Commission wants to continue cooperation with the U.S. in nanotechnology research and regulation to avoid divergent policies which could harm transatlantic cooperation and trade. Given the Community's possible influence over global approaches to nanotechnology, USEU recommends we significantly increase our cooperation with the EU on this issue, considering that:

-- The Commission is divided on nanotechnology regulation, with DG Enterprise believing existing regulation probably is sufficient to deal with new products as they approach the marketplace, whereas DG Environment favors new regulation, possibly to include labeling or moratoria on the release of new products until further information is available;

-- while the OECD will remain the primary forum in which to address existing information gaps without dampening the investment climate, we need to influence the EU and member state views in Brussels, Paris and other capitals;

-- we should capitalize on the Slovene Presidency's enthusiasm for nanotechnology by promoting cooperative scientific efforts and come to resolution on key areas of concern through venues such as the Transatlantic Economic Council.

¶2. (SBU) Bilateral engagement in the near future is crucial to ensure U.S. leadership of, and a coordinated transatlantic approach to, the development of a measured approach to nanotechnology regulation and policy. As a first step, USEU recommends we arrange for a USG interagency team to meet with key Commission Directorates General in Brussels on the margins of the March International Dialogue on Nanotechnology Research. OECD's two Working Parties dealing with nanotechnology also present opportunities. End summary

USEU Perceptions of Commission Nano-think

¶3. (SBU) The European Community and member states place a very high priority on nanotechnology research and development. For the period 2007-2013, the European Commission has allocated over EUR 3.5 billion to

nanotechnology related projects in addition to the individual member state funding of over EUR 650 million per year combined - Germany alone contributes EUR 330 million per year. These figures are comparable with those of the U.S. and Japan, the other two largest contributors to nanotechnology research worldwide. This concentration throughout Europe will lead to an increased role worldwide in determining global nanotechnology regulation. Though no final decisions have been made, possible avenues the EU could choose range from simply using the regulation which currently exists as it applies to sectors affected by nanotechnology to moratoria on research and development of nanotechnology and nano-containing products within certain sectors, which could include limitations or prevention of imports in these sectors. Intermediate steps include placing no additional limitations on release to market so long as all nano-containing products include mandatory labeling or requiring detailed life-cycle studies before a product can come to market. The decisions the EU takes in the coming years could have very dramatic effects on the global nanotechnology industry.

¶4. (SBU) Indeed, the Commission is increasingly absorbed with debates about how it should best regulate the technology, with a tendency toward a more politically-correct "precautionary" approach, in part because the Commission often focuses on Eurobarometer studies of European public opinion to guide policy formulation rather than taking it as a signal that more public debate and communication may be necessary. This comes through most clearly in the Commission's September 2007 Communication on Nanosciences and Nanotechnologies, when the Commission states that "The Commission's role as a policy making body is to take account of people's expectations and concerns" and that there "should also be public consensus on their overall impact." Even in

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the area of medical technologies, where the Community tends to take more of a risk-based approach, the Commission's European Group on Ethics in Science and New Technologies said in its January 2007 opinion on nanomedicine that the EU needs more research on safety and ethics, and recommends the setting up of a European network on the ethics of nanomedicine. The Commission does recognize that presenting accurate information on expected benefits and potential risks, and presenting opportunities for public debate, is crucial to the public's formulation of an independent view.

¶5. (SBU) Based on numerous meetings with Commission officials, diverging perspectives on regulation are apparent. DG Enterprise maintains the European Commission lead on regulatory review of nanotechnology and holds a position most similar to that of most USG agencies; however DGs SANCO (Health and Consumer Protection), Research, and Environment, which all have regulatory influence, appear to have diverging views. DG Enterprise believes existing regulation is sufficient for the vast majority of new products, though this regulation should be reviewed periodically to verify that it accounts for all new products. Cornelius Brekelmans from DG Enterprise provided the "EU Perspective on Policy and Regulatory Issues" during DG SANCO's October 2007 First Annual Safety for Success meeting, which brought together European and U.S. government officials, experts from the research and industry communities, and NGOs to discuss the current state of nanotechnology and understanding of risk assessment and risk management, (See <http://www.conf-sanco.eu/> for the program and presentations of the conference.) Brekelmans defined the EU perspective as a "safe, integrated, and responsible approach," explaining that health, safety, and environmental aspects of nanotechnology are covered by current EU regulatory framework; and that he expects most future EU action to occur at the level of additional supporting documents that more clearly define the existing framework using scientific findings, legal guidance, and other external inputs.

16. (SBU) DG SANCO under Director General Robert Madelin generally shares the DG Enterprise outlook and often collaborates with DG Enterprise in supporting a pragmatic risk-based approach to nanotechnology development. DG SANCO has a robust ongoing dialogue with FDA, and has been increasing contact with CPSC. FDA's presentation given by Dr. Richard Canady during the Safety for Success meeting explaining current FDA regulatory approaches and the reasoning behind why certain decisions are being made was very well received by both the Commission and the public. It appeared that while some in the audience - notably from the NGO community - still do not agree with FDA's approach, they appreciated the method by which the process was explained and the reasons for which FDA has made some of its regulatory decisions.

17. (SBU) DG Environment generally focuses on the effect on the environment throughout the lifecycle of a product, from manufacturing to disposal. This approach provides DG Environment with a tendency toward "precaution" and multiple opportunities to call for regulation. Eva Hellsten, now the scientific advisor to the Director General of DG Environment covering several topics, including nanotechnology, has indicated during meetings with USEU Econ officers that her DG leans in favor of blanket regulation on all nanotechnology products, possibly to include full labeling, limitations on the types of products released to market, or moratoria on products released to market until all properties are known fully. (Note: Ms. Hellsten prides herself on being one of the founding authors of REACH, the chemical regulation regime used by the EU that operationalizes the precautionary principle to the detriment of a pragmatic scientifically based approach. Additionally, she was co-author on an encyclopedia of chemicals regulation in Sweden, including indicating a preference toward labeling. She appears to be continuing this line of reasoning on nanotechnology regulation, including stricter efforts to prevent possible negative effects of products on the market. End note.)

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Follow-up meetings with Henrik Laursen, the new DG Environment desk officer for nanotechnology, support the idea that DG Environment is in favor overall of the precautionary principle. In meetings with USEU officials, Mr Laursen has explained that he believes the U.S. will see the "beauty" of REACH and will develop a similar regulatory strategy, and this thinking probably will drive DG Environment's position on nanotechnology.

18. (SBU) Somewhere between DGs Enterprise and SANCO and DG Environment is DG Research, which has no regulatory authority, but a substantial amount of influence within the Commission. It generally is in favor of innovation, having committed over EUR 2 billion to research, but at the same time, has released the guidelines for a voluntary code of conduct on research. DG Research recently hosted a conference, "Towards a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research," which focused on European efforts, specifically those by DG Research, to implement a voluntary code of conduct on nanotechnology research and those by industry to implement a similar measure within the commercial sector. (See ec.europa.eu/research/consultations/list_en.html for the full text.) Peteris Zilgavis, the Head of Unit for Ethics in DG Research, led the discussion for the Commission. He explained that nanotechnology present substantial benefits, but the DG decided on a code of conduct in response to a demand and expectation from civil society to guarantee the safe, ethical, and efficient development of nanotechnology. (Note: DG Research may be highlighting some of the possible risks of nanotechnology in part to attract more funding for research efforts to answer the knowledge gaps. End note.)

19. (SBU) Not surprisingly, this divergence among the Commission Directorates-General is reflected in the European public debate on nanotechnology. DG Enterprise is influenced

by industrial comments and views; while NGOs such as Greenpeace, Friends of the Earth, and Which? appear to drive actions by both DG Research and DG Environment. Specifically, industry wants a more hands off approach, explaining that existing regulation is sufficient to cover new products coming to market, and that industry inherently self-regulates to guarantee its products can remain on the market. Large NGOs such as Greenpeace and Friends of the Earth are driving for further regulation and more input as to government decision making, often contributing to Commission conferences such as those organized by DGs SANCO and Research. Frequent themes are the public's right to define "no-go" areas in research and consumer products, the use of the precautionary principle when faced with a lack of information, and providing further information to the consumer, preferably through the use of labeling. During DG Research's code of conduct meeting, these NGOs argued strongly that there should be restrictions on research activities according to public opinion; whereas industry and the majority of researchers preferred freedom to investigate any areas or applications.

¶10. (SBU) These internal differences have limited EU decision making on the way forward for regulating nanotechnology. The Commission was expected to release a communication last fall detailing the current state of nanotechnology related regulation in Europe and paths forward. However, this document has been delayed indefinitely, although we now expect to see the paper before the end of February. DG Environment's Laursen explained that the Communication has been downgraded to a Staff Working Paper, a document providing current thinking by the Commission on a topic, but not a binding position paper. He explained that Commissioner Guenter Verheugen was the driver for the change, wanting to "test the waters" before coming to a committed stance.

Existing Cooperation and Future Opportunities

¶11. (SBU) Despite the differences on regulatory approach,

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separate meetings between USEU Econ officers and all four DGs indicate that the Commission is in favor of further cooperation with the U.S. on a broad number of nanotechnology related issues. The topic has high-level political backing here, with references "to foster the exchange of information on nanotechnology" both in the 2007 U.S.-EU Summit declarations and the November 2007 Transatlantic Economic Council meeting, which contribute to the priority status of the issue within the Commission. Several DG Research officers explained that their work-plan in relation to the U.S. is driven almost entirely by these declarations and a need to produce concrete results.

¶12. (SBU) Furthermore, the Slovenian Presidency, which will have the Council presidency seat during both the Summit and Transatlantic Economic Council meeting in the first semester of 2008, has identified nanotechnology research as a priority - in part to promote the Josef Stefan Institute, which is one of the few nanotechnology doctoral programs worldwide. Dr. Vito Turk, the President of the Institute, explained to Embassy Ljubljana and a visiting USEU officer that he is strongly in favor of cooperation with the U.S., and he would like to expand collaborative efforts to include researcher and student exchanges. We can build on this interest to promote nanotechnology in the TEC meeting and further scientific collaboration with Europe during the Presidency.

¶13. (SBU) Renzo Tomellini, Head of Unit for Nanotechnology in DG Research has indicated during meetings with USEU Econ officers that he would be receptive to further efforts to perform joint research projects - the 7th Framework Program gives priority to research cooperation with an international dimension - or to joint workshops in which experts share

their results and projects. Priority topics for the Commission are in environmental, health, and safety issues, and DG Research often references toxicology and risk assessment as opportunities for cooperation, both in the OECD and as new bilateral efforts. Additionally, both DG Research and DG Enterprise would be receptive to efforts to develop new methodologies and standards for nanomaterials testing for use in these assessments.

Comment and Recommendation

¶14. (SBU) USEU shares the concern that many, particularly in industry, have shared with us that the Community may adopt an overly "cautious" regulatory approach to nanotechnology, as it has done in the area of agricultural biotechnology. The divisions within the Commission provide us an opportunity now to try to influence the outcome of the policy debate, but we will only succeed in doing so if we aggressively engage Commission policy makers now.

¶15. (SBU) To some extent, we are doing this now in the OECD, where the USG, the European Commission, and European Union member states are actively engaged in efforts to develop research strategies, communicate research efforts, define safety test guidelines and collaborate on nanomaterials testing through the Working Party on Nanotechnology and the Working Party on Manufactured Nanomaterials. It is very much in our interest to expand and highlight the collaborative work being done in these fora (which also involve the private sector and other NGOs), as the momentum gathering in them can be used to build confidence among Europeans that we are appropriately addressing concerns, thereby limiting appeals for application of the precautionary principle and a need to regulate to fill remaining gaps.

¶16. (SBU) But even as we build confidence in the OECD and member states for our processes and efforts to fill information gaps, we need to find opportunities to lessen the impact in the EU of NGO opposition to fully open research and innovation. We need to reinforce those in the Commission that are comfortable using science-based approaches as opposed to the precautionary principle if we are to have more

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influence over the Commission's regulatory stance. This should also help us reinforce Commission efforts to communicate to the European public our shared methods and reasoning for using existing regulation to cover the vast majority of products and what we are doing collaboratively to fill what gaps remain.

¶17. (SBU) The 3rd International Dialogue on Research and Development of Nanotechnology will be held in Brussels in March. This meeting will bring together government decision-makers on nanotechnology research from all countries with robust nanotechnology research programs. We recommend arranging a meeting on the margins of the International Dialogue to bring together representatives from USG agency stakeholders in nanotechnology with counterparts from DGs Enterprise, Research, SANCO, and Environment. USEU believes this meeting could approach key topics of interest of nanotechnology, including discussions of our efforts in OECD, how we can approach future bilateral research programs, and our current stances on nanotechnology regulation. Specifically, these discussions should focus on environmental, health, and safety efforts which are most likely to drive future regulatory actions in higher priority sectors such as chemicals, medicines, food, and cosmetics. Although some uncertainties about our own approach remain, the USG has a much more coherent position than the Commission, and, as Dr. Canady's presentation for FDA at the DG SANCO conference demonstrates, the USG can help drive how the Commission approaches nanotechnology over the coming years by presenting a compelling case that our approach is

effective and that they must ensure future regulatory efforts are not divergent. We should also use this occasion to focus on the importance of public education, and our sense of the most effective approaches to this, for this is one area where the Commission, and the Community more generally, are seriously deficient.

118. (SBU) In that regard, we should use the presence of our policy makers at the International Dialogue to engage NGOs - in Brussels and elsewhere in Europe - on this issue. While these organizations tend to be dogmatic, there are areas where they may be willing to be more flexible, specifically on certain sectors where nanotechnology is applied and on labeling. During DG Research's Code of Conduct conference, for instance, the Greenpeace representative acknowledged that the risks of nanotechnology are very different depending upon the sector, and that inevitably, these discussions need to take place on a sector specific basis, and not generically on nanotechnology. On labeling, it appears the concern is more about information to the consumer, and labeling is one obvious method to address this concern. However, NGO reps seem amenable to presentation of other methods of providing information that proves there is no attempt to hide information. USEU and the EUR PD Hub in Brussels have facilities to help our policymakers reach the European media and the European NGO community; we should take advantage of this.

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